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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Levamisole Hydrochloride Soluble Drench Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Agri Laboratories, Ltd. The ANADA provides for use of levamisole hydrochloride soluble drench powder for use in water as an anthelmintic for cattle and sheep.

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register**.)

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503–0103, filed ANADA 200–225 that provides for use of Prohibit™ (levamisole hydrochloride) soluble drench powder, in 46.8 and 544.5 gram packages, in water, as an anthelmintic for cattle and sheep. Levamisole cattle and sheep drench is used to treat infections of stomach worms (*Haemonchus, Trichostrongylus, Ostertagia*), intestinal worms (*Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum*) (*Chabertia*, sheep only), and lung worms (*Dictyocaulus*). Agri Laboratories, Ltd.'s ANADA 200–225 is approved as a generic copy of the Schering–Plough Corp.'s NADA 112–051 Levasole® (levamisole) soluble drench. ANADA 200–

225 is approved as of August 27, 1998, and § 520.1242a (21 CFR 520.1242a) is amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In the regulations, § 520.1242a provides for use of levamisole hydrochloride soluble powder in a drench as an anthelmintic for cattle and sheep against stomach worms, intestinal worms, and lung worms, and in drinking water as an anthelmintic for swine against large roundworms, nodular worms, intestinal threadworms, and lungworms. The regulation states the drug's chemical name and assay, information that FDA has determined is better provided by other references. In addition, the rule fails to properly reflect the dosage. Thus, FDA is amending § 520.1242a to remove the chemical name and assay and to better reflect the package sizes and dosage. Finally, FDA also is redesignating the paragraphs to reflect current style format.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.1242a is amended by removing paragraphs (a) and (d), by redesignating paragraphs (b), (c), (e), and (f) as paragraphs (a), (b), (c), and (d), respectively, and by revising newly redesignated paragraphs (a), (b), (c), (d)(1)(i), (d)(1)(iii), (d)(2)(i), and adding newly designated paragraph (d)(2)(iii) to read as follows:

§ 520.1242a Levamisole hydrochloride drench and drinking water.

(a) *Specifications.* Each package contains either 9.075, 11.7, 18.15, 46.8, or 544.5 grams of levamisole hydrochloride.

(b) *Sponsors.* Approval for sponsors in 21 CFR 510.600(c) for use as in paragraph (d) of this section as follows:

(1) See 043781 for use of 46.8 gram package as in paragraph (d)(1) of this section, for 11.7 and 46.8 gram packages as in paragraph (d)(2) of this section, and for 9.075 and 18.15 gram packages as in paragraph (d)(3) of this section.

(2) See 000061 for use of 46.8 and 544.5 gram packages as in paragraph (d)(1) of this section, for 11.7, 46.8, and 544.5 gram packages as in paragraph (d)(2) of this section, and for 18.15 gram package as in paragraph (d)(3) of this section.

(3) See 057561 for use of 46.8 and 544.5 gram packages as in paragraphs (d)(1) and (d)(2) of this section.

(c) *Related tolerances.* See § 556.350 of this chapter.

(d) *Conditions of use.* It is used as an anthelmintic at 0.365 gram per 100 pounds of body weight as follows:

(1) *Cattle*—(i) *Amount.* As a single oral dose drench using 46.8 or 544.5 gram packet.

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(iii) *Limitations.* Conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after the first treatment. Do not slaughter for food within 48 hours of treatment. Not for use in dairy animals of breeding age. Consult your veterinarian before using in severely

debilitated animals. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Prepare solutions for use as follows:

(*a*) Dissolve contents of 46.8 gram package in water to provide 1 quart (32 fluid ounces) of drench solution and administer as a drench at 1/4 ounce per 100 pounds of body weight as a single oral dose.

(*b*) Dissolve contents of 46.8 gram package in water to provide 8.75 fluid ounces of concentrate solution and administer as a drench at 2 milliliters per 100 pounds of body weight as a single oral dose by syringe.

(*c*) Dissolve contents of 544.5 gram package in 3 liters of water and administer as a drench at 2 milliliters per 100 pounds of body weight as a single oral dose.

(2) *Sheep*—(i) *Amount.* As a single oral dose drench using 11.7, 46.8, or 544.5 gram packet.

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(iii) *Limitations.* Conditions of constant helminth exposure may require retreatment within 2 to 4 weeks after the first treatment. Do not slaughter for food within 72 hours of treatment. Consult your veterinarian before using in severely debilitated animals. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Prepare solutions for use as follows:

(*a*) Dissolve contents of 11.7 gram package in 1 quart (32 ounces) of water and administer as a drench at 1 ounce per 100 pounds of body weight, or dissolve in 10.9 fluid ounces of water and administer as a drench at 1 milliliter per 10 pounds of body weight as a single oral dose.

(*b*) Dissolve contents of 46.8 gram package in 128 fluid ounces (1 gallon) of water and administer as a drench at 1 ounce per 100 pounds of body weight as a single oral dose.

(*c*) Dissolve contents of 544.5 gram package in 3 liters of water and administer as a drench at 2 milliliters per 100 pounds of body weight as a single oral dose.

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Dated: 10/23/98
October 23, 1998

SFS/ff

Stephen F. Sundlof
Director
Center for Veterinary Medicine

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